Sub D27

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Cont'd

REMARKS

The Office Action dated November 20, 2001 has been received, its contents carefully noted, and the applied citations thoroughly studied. Accordingly, the foregoing revisions to claims are tendered with the conviction that patentable contrast has now been made manifest over the known prior art and certain typographical inexactitudes have been rectified. Accordingly, all rejections tendered by the Examiner in the above-referenced Office Action are hereby respectfully traversed and reconsideration is respectfully requested.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 12 through 23 and 56 through 62 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

More specifically, the Examiner found, in claims 19 and 20, that the term "the recess formed in the sheet" lacks antecedent basis, stating that the recess was associated with the mold, but not the sheet itself. Applicant respectfully submits that the recess from the mold is transferred to the sheet in the process, and thus, after the process, the sheet contains a recess complemental to that of the mold. Claim 19 has been amended to make explicit that which was heretofore only implicit, now reciting that the blank sheet not only conforms to the mold, but also this conformation includes a recess in the conformed sheet.

The Examiner further states that it is unclear what class of statutory invention the applicant is claiming, because the preamble of claims 19 and 60 states that the invention is drawn to a method of forming a bag, but claims 58, 59, and 62 appear to be drawn to a method of using the bag.

The Examiner has inadvertently touched upon the essence of the invention: a bag which, once formed, is breakage resistant, particularly when filled with a fluid and is frozen. Please recall that the Examiner mandates the different classes of invention — not applicant. Applicant should not be penalized because the invention does not fall neatly into a statutory invention class. If anything, this is strong evidence of invention.

Finally, the Examiner refers to the language in claim 23 that specifies the formation of a plurality of portals, finding it unclear whether the applicant is claiming the step of forming a plurality of portals or merely the formation of a single portal, because the applicant specified only a singular recess for the first and second molds. Claim 23 has been deleted. Claim 19, from which prior claim 23 depended, has been amended to recite that the mold includes at least one portal-shaped recess that forms a portal that passes into the interior of the bag.

It is respectfully submitted that there is only one illustrative recess in the mold; the recess, by definition, must include a portal-shaped recess to produce an access-providing portal. The portal-shaped recess or recesses must coincide to result in a portal that accesses the interior of the bag. It is hoped that this amendment and explanation provides sufficient information to clarify that which the applicant claims as his invention, and the rejection under 35 U.S.C. §112 is no longer applicable.

Undersigned wishes to make explicit that this revision is not be construed as a *Festo*-type narrowing. Rather, the revisions are intended to assure conformance with 35 U.S.C. § 112 in general and paragraph 2 in particular.

Rejections under 35 U.S.C. §102

The Examiner has rejected claim 19 under 35 U.S.C. §102(b) as being anticipated by Medwed (USP 4,397,804).

With respect to rejections under 35 U.S.C. § 102, the Examiner is invited to consider the following binding, compelling precedent articulated by the Court of Appeals for the Federal Circuit:

". . . anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference." *Akzo N.V. v. United States ITC*, 808 F.2d 1471, 1 U.S.P.Q.2d 1241 (Fed. Cir. 1986).

Further, "those elements must either be inherent or disclosed expressly . . ." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987). ". . . and must be arranged as in the claim[s] . . ." *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 231 U.S.P.Q. 644 (Fed. Cir. 1986).

In addition, ". . . [the] absence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986).

The Examiner claims that the containers formed in Medwed are analogous to those formed by the instant invention. In the abstract of the patent, Medwed describes "stable containers of uniform wall thickness [that] will be produced." In the specification, he declares that an object of his invention is to produce "containers having

edge and corner portions of appropriate thickness to achieve satisfactory rigidity" (col. 1, lines 51-52).

Medwed is totally unconcerned with molds that provide fracture resistant medical bags, but instead teaches the manufacture of containers used for packaging food (column 1, lines 9-10). Medwed does not see the structure associated with his invention as being a possible solution to improve medical bags to make them "strong enough to withstand rough handling without breaking". Nowhere in Medwed does he provide any teaching whatsoever of making a container having any utilitarian function in the medical industry. The problem Medwed solves pertains to the food industry. As a direct consequence, Medwed is non-analogous art, particularly when viewing the claims as amended hereinabove.

Medwed drawn to claim A which is mere method of forming bag

Moreover, the bags produced by the method of the present invention are not rigid like the containers of Medwed. As mentioned above, the instant invention produces improved medical bags that are "strong enough to withstand rough handling without breaking". The bags are molded, but retain "memory" of their shape (specification page 10, line 27 through page 11, line 2) and may be manipulated to move enclosed substances within the bag (see specification, page 10, lines 9-10). Thus, even if Medwed were analogous art, the present invention would not be anticipated by its teachings. The rejection under 35 U.S.C. § 102 should be withdrawn.

Rejections under 35 U.S.C. §103

The Examiner has rejected claims 19 through 23, 56, 57, 60, and 61 under 35 U.S.C. § 103(a) as being unpatentable over Sneider (USP 4,591,357) in view of Heck (USP 4,428,743) "with or without" evidence from Nathoo (USP 4,943,222) or Medwed, and as being unpatentable over Falk (USP 5,108,387) in view of Heck (USP 4,428,743) "with or

without" evidence from Nathoo (USP 4,943,222) or Medwed. At the outset, undersigned respectfully submits that the Examiner's caprice in citing references under 35 U.S.C. § 103 is confusing. If the instant invention is obvious "with or without" a particular reference, its inclusion is superfluous and irrelevant, or the initial combination of references is deficient. Such citation burdens the record and obscures the issues during prosecution, which needlessly prolongs the process and creates unnecessary work for both the Examiner and applicant.

Undersigned takes mild exception to all of the Examiner's combinations of references because they appear to be based on perhaps the inadvertent but nonetheless improper use of hindsight. As the precedents above compel, this is tantamount to penalizing the inventor by using his own patent specification against him in providing the basis for assembling the mosaic of elements the Examiner has preferred. Clearly there is no such teaching in the prior art.

Undersigned has read these patents carefully and has failed to uncover the basis by which the Examiner has combined these references to support an obviousness type rejection. Stated alternatively, there is no teaching within these citations that would warrant the combination of elements proposed by the Examiner and it is respectfully stipulated that applicant's structure would still not be obtained thereby. A specific teaching within one of the references suggesting the combination is required:

Undersigned provides the Examiner guidance with respect to rejections under 35 U.S.C. § 103 which is binding, compelling precedent from the Court of Appeals for the Federal Circuit.

"When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other

than the hindsight gleaned from the invention itself." *Interconnect Planning Corp. v. Feil*, 774 F.2d at 1143, 227 U.S.P.Q. at 551. Citing *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n. 14, 221 U.S.P.Q. 929, 933 & n. 14 (Fed. Cir. 1984).

"Something in the prior art as a whole must suggest the desirability and thus the obviousness of making the combination." *Lindemann Mashcinenfabrick GmbH v. American Hoist and Derrick Co.*, 780 F.2d 1452, 1462, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984).

"It is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention." *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 437 F.2d 1044 (Fed. Cir. 1988).

These precedents, which are recent decisions from the Court of Appeals for the Federal Circuit are binding precedents with respect to the manner in which patents showing the prior art can be combined. When relying on these principles, it is apparent that the prior art cannot be combined as the Examiner has proposed because there is no teaching suggesting such a combination.

It is Black Letter Law the Patent and Trademark Office's burden is to establish a prima facie case of obviousness. The Patent and Trademark Office has met its burden only when it fully describes: "1) What the reference discloses, teaches and suggests to one skilled in the art; 2) What the reference lacks in disclosing, teaching or suggesting vis-à-vis the claimed features; 3) What particular teaching or suggestion is being relied upon either via a reference itself or knowledge of person of ordinary skill in the art; 4) A statement explaining the proposed modification in order to establish the prima facie case of obviousness; and finally 5) the motivation behind the statement of obviousness which comes from three sources: a) teachings of the prior art; b) nature of the problem

to be solved; or c) knowledge of persons of ordinary skill in the art", *see In re Rouffet* 47 USPQ2d 1453 (Fed. Cir. 1998).

The Examiner has failed to meet these threshold requirements to establish prima facie obviousness:

> "Prior art reference, in order to be relied upon as basis for rejecting applicant's invention, *must either* be *in field of applicant's endeavor or, if not, be reasonably pertinent to particular problem with which inventor was concerned*; combination of elements from non-analogous sources, in manner that reconstructs applicant's invention only with benefit of hindsight, is insufficient to present prima facie case of obviousness." *In re Oetiker*, 24 U.S.P.Q.2d 1443. [Emphasis added.]

In the absence of such a prima facie showing, the Examiner's rejection cannot stand:

> "Decision rejecting claims in utility application as obvious over combination of prior art references *must be reversed*, since obviousness analysis in decision is limited to discussion of ways that multiple references can be combined to read on claimed invention, but *does not particularly identify any suggestion, teaching, or motivation to combine references, and does not include specific or inferential findings concerning identification of relevant art, level of ordinary skill in art, nature of problem to be solved, or any other factual findings that might support proper obviousness analysis*." *In re Dembiczak*, 50 U.S.P.Q.2d 1614. [Emphasis added.]

While Sneider is directed to the medical practice, it does not contain all the elements of the present invention, as the Examiner acknowledges at page 5 of the Office Action. Sneider's container is used to protect handlers when mixing drug substances together. The center portion of the container is connected to, and contains, a rigid container, contained in a sufficiently stable manner so as not to produce mixing of the contents before the desired time. No such device is contemplated in the instant invention.

applicant

At page 5 of the Office Action, the Examiner claims that "Sneider discloses a container having a planar wall, a radiused periphery, and a peripheral ledge which retains its shape." No proof that Sneider retains its shape is offered, and there is no indication of the particular shapes that characterize the container of the present invention in the disclosure of Sneider. Few details are given regarding the construction of Sneider's envelope-shaped container, other that it contains liquid without breaking or leaking. Sneider gives no details of the seamed edge, which are crucial to redirecting the phase change forces experienced by the container of the instant invention. The fact that a container contains liquid without rupture is not indicative of that container's physical behavior when subjected to extreme forces in non-ambient conditions. Thus, Sneider does not contain all of the elements of the present invention, nor does it provide the benefits thereof.

Also at page 5 of the Office Action, the Examiner cites Heck for teaching that "medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves." It is respectfully submitted to the Examiner that this general statement of formation technique without regard to the ultimate use or operating environment of a container does not provide sufficient motivation to combine such a reference with any other. Even if this were a specific teaching that provided sufficient motivation for combination, mere formation technique such as that cited here by the Examiner (blow molding or vacuum molding) would not cure the deficiencies of the Sneider patent with regard to the present invention.

Using what is old in the art wouldn't be obvious?

The Examiner has also cited the patent to Nathoo, and undersigned respectfully submits that Nathoo has no relevance here. The Examiner states, "Nathoo evidences

that vacuum molded halves are less susceptible to tearing" (page 5 of the Office Action), and cites Nathoo's abstract for this proposition.

This assertion suffers from the same problem as the Examiner's assertion with regard to Heck, discussed hereinabove. Here, the Examiner makes a general assertion about properties for formed items without evidence and without consideration of the details of the formation methods. Not all vacuum-molding methods produce suitable results for all applications.

Nathoo teaches laminate assembly utilizing elastomeric sheets that conform to the mold. Between each molding cycle, the molds separate, and the sheets remain in place, not conformed to the molds, but positioned between them. The molding technique uses fiber-based preform materials (col. 4, lines 42-46) that have nothing to do with the present invention. Even if the Examiner's assertions were appropriate, Nathoo is non-analogous art.

Moreover, it is the very unsuitable nature of conventional techniques discussed in Heck and Nathoo that has prompted the applicant to delve into the art. Applicant claims a method unlike that of the prior art.

Falk is directed to a collapsible container that retains its shape as it is emptied while resting on a surface. The changeable nature of the shape of Falk's container prevents uniformity in the sidewall area adjacent to the seam, which will necessarily adjust upon collapse. Thus, Falk does not provide the correct geometry to distribute the phase change forces, because of its inherently adjustable/collapsible nature. The planar surface provided in the instant invention helps maintain as little temperature gradient as possible when storing multiple such bags together. The geometrical

properties of Falk's container are dependent on the surface upon which the container rests.

It is respectfully submitted that a container that collapses in this manner cannot maintain the construction in the present invention adapted to respond to phase change forces. Because Falk's container is designed to collapse, the container volume may not exhibit predictable behavior upon filling and freezing, and because there is no consideration of such behavior, Falk is not applicable to the instant invention.

With regard to the combination of Falk with Heck and Nathoo and/or Medwed, the deficiencies of the latter three patents are discussed above. The attributes of these patents similarly do not cure the problems of Falk.

Finally, with regard to the Examiner's claims at pages 5 and 6 of the Office Action with regard to claim 60 and the abovementioned patents, the Examiner merely states that "a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change." Even if this statement were true, the cited patents do not disclose containers of the same shape as the present invention, and the rejection under 35 U.S.C. § 103 should be withdrawn.

The present invention discloses a method of making the containers designed to produce containers of a particular conformation. Not all formation methods would produce a container suitable for handling phase change forces. As mentioned above, it is the unsuitability of the prior art that calls for a new solution with respect to techniques and apparatus concerning material actively undergoing phase changes.

In view of the foregoing, it is respectfully requested that the Examiner pass this case to issue. If, upon further consideration, the Examiner believes further issues remain outstanding or new ones have been generated, undersigned respectfully requests that the Examiner call undersigned to expeditiously resolve same.

Dated: May 20, 2002

Respectfully Submitted:

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Bracketed and Underlined Claims under 37 C.F.R. § 1.121(c)(1)(ii)

Claim 19 (twice amended) - A method for forming a bag, the steps including:

forming a first mold having at least one portal-shaped recess and a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface, whereby a portal formed by said portal-shaped recess passes into an interior of the bag,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold[,] and retain[ing] its conformation, whereby a conformed sheet includes a recess that includes [including] a planar surface, radiused periphery and peripheral ledge,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Claim 60 (amended) - A method for forming a medical bag which is resistant to forces engendered by medical fluid undergoing a phase change within the bag, the steps including:

forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface,

placing a blank of sheet material over said mold, and causing the blank to conform to the mold[,] and retain[ing] its conformation, including a planar surface, radiused periphery and peripheral ledge,

removing the conformed sheet from the mold, and

closing the recess formed in the sheet with another sheet parallel to the planar surface such that the radiused periphery dissipates forces during phase change.

Claim 61 (amended) - The method of claim 60 including forming at least one closeable portal in the bag.

Claim 62 (amended) - The method of claim 61 including filling the bag with a thermolabile biological fluid and freezing the fluid in the bag.